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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,100	12/28/2001	Erik Ho Fong Wong	00378.US1	1691

25533 7590 03/29/2004

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,100	ERIK HO FONG WONG ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3,7-9,11-13,15,16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-9,11-13,15,16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's Amendment and Response filed December 18, 2003 is acknowledged. Claims 2, 5, 6, 10, 14, 17 and 19-22 are canceled. Claims 1, 3, 4, 7-9, 11-13, 15, 16 and 18 remain under consideration.

An Information Disclosure Statement filed December 18, 2003 is further acknowledged and has been reviewed.

The disclosure was objected to in the last Office Action because claims 1 and 22 were asserted to be substantial duplicates. Following the cancellation of claim 22, the objection of record is withdrawn.

Claims 1-22 were rejected in the last Office Action under judicially created doctrine as being drawn to an improper Markush group. Following amendments to claims 1 and 9, wherein the neuroleptic agents are now limited to clozapine, olanzapine and risperidone, this rejection of record is withdrawn.

Claims 9-17 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and practice the invention. Following amendments to claims 1 and 9, wherein the neuroleptic agents are now limited to clozapine, olanzapine and risperidone, this rejection of record is withdrawn.

Claims 19-21 were rejected in the last Office Action under both 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101, directed to use claims. Following the cancellation of claims 19-21, these rejections of record are moot.

Applicants' arguments with respect to the rejection of claims 1-22 under 35 U.S.C. 103 as being unpatentable over Koch et al., Eur. J. Clin. Pharmacol. (abstract),

in the last Office Action, have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 7-9, 11-13, 15, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bymaster et al., EP 0 830 864.

Bymaster teaches combination compositions comprising an atypical antipsychotic agent and a serotonin reuptake inhibitor and therapy for treatment of schizophrenia. See page 12, lines 50-51, as well as the various combinations at the bottom of page 3. The claims differ in that Bymaster does not recite the serotonin reuptake inhibitor reboxetine. However, in view of Bymaster's teaching, one skilled in the psychiatry art would have been motivated to prepare and administer a combination composition comprising clozapine, olanzapine or risperidone with reboxetine to treat schizophrenia. Such would have been obvious in the absence of evidence to the contrary because the prior art establishes efficacy in the treatment of schizophrenia when a combination of a serotonin reuptake inhibitor and one of the three specific atypical antipsychotic agents is administered. Further, motivation to combine the selective serotonin reuptake inhibitor reboxetine flows from its advantageous side effect profile and low likelihood of drug interactions. In the treatment of depression reboxetine is well tolerated in elderly patients and cardiovascular and respiratory effects are rare.

The determination of optimal optical isomers, dosages, modes of administration and delivery vehicles are parameters well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Applicants' amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

March 25, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER